2000.01 HEALTH POLICY AND PROTECTION BRANCH REGULATIONS

A. Public Participation in Defining Health Policy

Whereas: the Health Protection Branch (HPB) of Health Canada is currently engaged in a process to renew its health protection program; and

Whereas: the HPB of Health Canada is asking the public for ways to participate fully and effectively in the development of health policy or regulations, risk management decisions and/or program implementation; and

Whereas: the best time to ensure that our views are heard is before new regulations are drawn up and implemented; therefore, be it

RESOLVED: that the National Council of Women of Canada urge the Government of Canada to direct Health Canada to involve the public in the development of health policy by making available to interested groups and individuals information to facilitate participation in the formation of health policy and by holding accessible public forums/venues, including internet, for nation-wide participation with full disclosure of pros and cons and costs of public policy options.

B. Health Protection Branch Regulations

Whereas: the Health Protection Branch of Health Canada is in the process of modifying the health protection system by updating and changing the laws that govern its work; and

Whereas: Canadians are being invited to comment on the proposed changes; and

Whereas: industry's in-house testing of health-related products must be thoroughly reviewed and evaluated by acknowledged experts in the field who are on staff at the Health Protection Branch; therefore, be it

RESOLVED: that the National Council of Women of Canada urge the Government of Canada and Health Canada to ensure:

a. **that the regulations of the Health Protection Branch of Health Canada indicate that the Government of Canada is fully committed to protecting the health of Canadians; and**
b. **that the licensing of therapeutic products be based solely on scientific evidence from research carried out by internationally respected scientists within the Health Protection Branch; and**
c. **that the cost recovery for the assessment of new therapeutic products be a separate department that deals with financial matters; and be it further**

RESOLVED: that the regulations require the publication of possible negative results in regard to safety or deficiency results observed in clinical trials of new therapeutic products which are destined for market, in a peer-reviewed scientific journal along with dissenting views of other scientists. This obligation is not to be negated by a confidentiality clause with the manufacturer; and be it further

RESOLVED: that non-therapeutic products under its control be licensed for use in Canada only after rigorous testing over a sufficient period of time has assured the scientists of Health Canada that the products are safe for human health in the long-term and that there be a separation between the benefits of Canadian's health versus the benefits to commercial interests in the production of therapeutic products; and be it further

RESOLVED: that the use of therapeutic products which it has under license (such as antibiotics) be limited to their use as therapy; and be it further

RESOLVED: that there should be periodic reviews of the safety of these products rather that a system responsive only to complaints.

C. Reporting of Clinical Studies

Whereas: scientists conducting clinical studies on new therapeutic products may be constrained by their funding agencies from reporting unfavourable results; and

Whereas: negative results of safety and/or efficacy testing of therapeutic agents may be noted only in a small proportion of the test population and missed entirely in other studies; and

Whereas, the possibility of tragic consequences may be anticipated by such negative outcomes; and

Whereas: publication of results of clinical studies in peer-reviewed journals ensures that those results will be evaluated by many other scientists; and

Whereas: most manufacturers of new therapeutic products voluntarily withdraw them when a question of safety arises rather than risk costly lawsuits later; therefore, be it

RESOLVED: that the National Council of Women of Canada urge the Government of Canada and Health Canada to pass regulations that prohibit confidentiality clauses, between scientists conducting clinical evaluation and manufacturers or granting agencies, which would prevent the publication of unfavourable outcomes.

D. Inappropriate Use of Therapeutic and Non-Therapeutic Products

Whereas: the use of non-therapeutic products such as bovine growth hormone (rbST) may result in serious health problems for both animals and humans; and

Whereas: the safety of such products cannot be established in a short term period; and

Whereas: no urgent need for such products can be demonstrated; and

Whereas: the inappropriate use of therapeutic products such as antibiotics in animal feed has implications for the health of both animals and humans; therefore, be it

RESOLVED: that the National Council of Women of Canada urge the Government of Canada and Health Canada to support the precautionary principle in the evaluation and licensing of therapeutic and non-therapeutic products.